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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,284	10/06/2000	Sigrid Lise Fossheim	REF/FOSSHEIM/100	8494

7590 10/09/2002
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EXAMINER

WELLS, LAUREN Q

ART UNIT PAPER NUMBER

1617

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/680,284

Applicant(s)

FOSSHEIM ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-13 and 23-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-13 and 23-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The Amendment filed 7/16/02, cancelled claims 7-8, amended claims 2 and 6, and amended a paragraph on pg. 16 of the specification.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed 7/16/02 (Paper No. 11) to the rejection of claims 1-6, 9-13 and 23-38 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive.

The Applicant's amendment and arguments filed 7/16/02 (Paper No. 11) are persuasive to overcome the 35 USC 112 rejections in the previous Office Action. See below for details.

103 Rejection Maintained

The rejection of claims 1-6, 9-13 and 23-38 under 35 U.S.C. 103(a) as being unpatentable over Unger (6,315,981) in view of Ozer et al. (EP. Jn. Of Pharm. And Biopharm) or Sonek et al. (5,631,141) in further view of Unger (6,143,276) is MAINTAINED for the reasons set forth in the Office Action mailed 2/13/02, Paper No. 8, and those found below.

Applicant argues, "Unger I discloses an invention where not the microsphere matrix but the gaseous precursor inside the microsphere is responsive to temperature". This argument is not persuasive. First, the Examiner respectfully points out that this rejection was made in combination with Ozer or Sonek et al. to teach the responsiveness of the matrix to a pre-selected physiological parameter. As in the previous Office Action, the Examiner respectfully points out that a) Unger, Ozer and Sonek all teach vesicles comprised of phospholipids that can encapsulate active agents; b) Unger and Ozer teach vesicles comprised of the same phospholipids; b) and, Ozer and Sonek teach their phospholipids as undergoing phase transitions under the influence of

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increased temperature. Second, the Examiner respectfully points out phospholipids are known in the art to respond to changes in temperature. Biochemistry by Grisham and Garrett teach the following: "Lipids in bilayers undergo radical changes in physical state over characteristic narrow temperature ranges. . . These phase transitions involve substantial changes in the organization and motion of the fatty acyl chains within the bilayer".

Applicant argues, "The present invention, on the other hand, discloses that this phase transition temperature is used to design temperature sensitive liposomes which show increased permeability at this phase transition temperature". This argument is not persuasive, as it is not commensurate in scope with independent claims 1, 23, 37 or 38.

Applicant argues, "A person skilled in the art would not combine the teachings of Unger I and Ozer, because a stable microsphere matrix is a prerequisite of the teaching of Unger I, and the breakdown of the liposome matrix is a prerequisite of the teaching of Ozer". This argument is not persuasive. First, the Examiner respectfully points out that a stable microsphere does not correspond to a microsphere that does not undergo a phase transition. Is not the instant microsphere stable, and does not the microsphere of Unger I breakdown in the body? Second, The Examiner respectfully points out the microspheres of Unger I and Ozer are comprised of the same lipids, and would therefore exhibit the same properties.

Applicant argues, "In contrary to the present invention, Sonek does not disclose contrast generating species. Moreover, the method according to Sonek requires the biosensor to be placed inside the body, whereas the method according to the instant invention is a non-invasive method". This argument is not persuasive. The Examiner respectfully points out that Sonek was

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relied upon to teach that organic phospholipid bilayers, such as those taught by Unger I, undergo temperature-dependent phase transitions.

Applicant argues regarding Unger II, “Thus, bioactive agents are released. In contrary thereto, the present invention requires a matrix which is responsive to the change in temperature”. This argument is not persuasive, as Unger II was relied upon for his teachings of targeting cell adhesion molecules attached to microspheres containing gaseous precursors.

Notes/Suggestion

(i) The Examiner respectfully points out, in regard to claim 9, that contrast agents have the property of acting as a cell adhesion molecule. For example, tumor cells are bloated cells filled with water. As a result, contrast agents are preferentially attracted to these cells in comparison to normal cells.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell S. Travers can be reached on (703)308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
October 4, 2002


SREENI PADMANABHAN
PRIMARY EXAMINER 10/3/02